SAMPLING AND QUALITY ASSURANCE PROJECT PLAN
REVISION 1

FOR

Libby, Montana

Environmental Monitoring for Asbestos

Baseline Monitoring for Source Area and Residential Exposure
to
Tremolite-Actinolite
Asbestos Fibers

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DOCUMENT REVISION LOG

Revision	Date	Major Changes
0	12/6/99	--
1	1/4/00	a. Revised text to clarify study design and DQOs b. Added SOP for surface water to allow collection and evaluation of surface water as a transport medium c. Added alternative SOP for asbestos analysis in soil that may have higher sensitivity than other methods. d. Added figures to help illustrate key steps from sample collection to analysis e. Added final SOPs as appendices to the revision.

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A. PROJECT TASK ORGANIZATION

A3 PROJECT MANAGEMENT

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A4 PROBLEM DEFINITION and BACKGROUND

Problem: This sampling plan has been developed in response to requests from the State of Montana, Lincoln County Health Board (meeting minutes, 11/23/99), and City officials of Libby, MT, to address questions and concerns raised by citizens of Libby regarding possible ongoing exposures to asbestos fibers as a result of historical mining, processing and exportation of asbestos-containing vermiculite. Over 60 years of mining, milling, packaging and shipping of vermiculite at the mine and associated properties resulted in the environmental release of asbestos fibers during mining operations (McDonald et al., 1986; Amandus et al., 1987; Amandus

and Wheeler; 1987; Amandus et al., 1978). Since closure of the mine in 1990, it is expected that production-related emissions have been greatly reduced or eliminated. However, there are presently insufficient data to conclude that current exposures to residents in Libby and the surrounding area and occasional recreational visitors to the former mining areas are negligible. ***The purpose of this sampling effort is to acquire information suitable for supporting an exposure and risk assessment for current environmental conditions in Libby.***

Background: Asbestos is a generic term for a group of six naturally-occurring, fibrous silicate minerals that have been widely used in commercial products. Asbestos minerals fall into two groups or classes: serpentine asbestos and amphibole asbestos. Serpentine asbestos, which includes the mineral chrysotile, a magnesium silicate mineral, possesses relatively long and flexible crystalline fibers that are capable of being woven. Amphibole asbestos, which includes the minerals amosite, crocidolite, tremolite, anthophyllite, and actinolite, form crystalline fibers that are substantially more brittle than serpentine asbestos.

Asbestos is of potential health concern because chronic inhalation exposure to excessive levels of asbestos fibers suspended in air can result in lung disease such as asbestosis, mesothelioma, and lung cancer. Figure 1 presents a preliminary Site Conceptual Model which identifies exposure pathways by which asbestos fibers from mining-related sources might become entrained in air in Libby, leading to inhalation exposures of residents or workers. The site conceptual model will be refined as site data are acquired and an improved understanding of actual transport and exposure pathways is achieved.

Approach: This sampling plan describes the efforts planned by EPA to monitor and characterize asbestos-containing materials in and about the vicinity of Libby. The plan will be composed of two phases:

Phase 1: This is a rapid pilot-scale investigation that has two main objectives:

a) Obtain information on airborne asbestos levels in Libby in order to judge whether a time-critical intervention is needed to protect public health.

b) Obtain data on asbestos levels in potential source materials, and identify the most appropriate analytical methods to screen and quantify asbestos in source materials.

Phase 2: This will consist of a systematic evaluation of asbestos levels in air in Libby and in appropriate background locations, along with a systematic investigation to identify the actual or potential source(s) and release mechanism(s) of asbestos in Libby and the surrounding area. The implementation, pace and scope of Phase 2 and the methods used to collect and analyze samples in Phase 2 will be determined in large part by the results of the Phase 1 pilot study.

Interpretation. Analyses of asbestos fibers in air and other site media will determine the potential (or lack of potential) for human inhalation exposure under **present** conditions. The

environmental fate and transport of asbestos fibers may be such that present measurement conditions (e.g. weather) and/or measurement techniques interfere with the ability to identify and/or quantify asbestos fibers in relevant exposure media (soil, dust, air, or water). Thus, while conclusions drawn from the implementation of this study are applicable to the present conditions at the site, they do not necessarily reflect conditions which may develop in the future.

A5 PROJECT TASK DESCRIPTION

To the extent possible, sampling will be conducted such that data will be meaningful for human exposure and risk assessment. Because the chief exposure pathway is air, emphasis will be placed on collection of air samples. In addition, to help identify potential sources and transport pathways for asbestos, samples of various bulk materials (mine waste, soil, dust, water, sediment) will also be collected in residential and non-residential areas.

Phase 1

Basic tasks needed to complete Phase 1 are listed below:

1. Collect samples of air, soil, dust, water, and insulation from selected locations in and around town, including a number of residential and/or commercial locations, as well as suspected source areas such as historical mining/processing/loading facilities.

2. Perform asbestos analyses on all air samples and a selected set of the dust, soil, insulation and water samples (those judged to be most likely to have either “high” or “low” concentrations) in order to obtain preliminary information on asbestos levels in air and other media, and to identify the optimum conditions for collection and analysis of bulk media.

At this time, the proposed sampling for Phase 1 consists of collection of environmental media from approximately 30 residences and 3 potential source areas. Residential sample locations will be selected from residences volunteering for multimedia sampling. In addition to the collection of samples within the residential area, samples may also be collected in commercial warehouses, agricultural buildings, or businesses in Libby, as needed to support the objectives of the On Scene Coordinator. Potential source area samples will be collected along the mine road (Rainy Creek Road) and at the Former Vermiculite Loading facility near the intersection of Rainy Creek Road and Highway 37.

Media samples will be collected according to Standard Operating Procedures provided by CDM, Inc. or as provided in the attachments to this Sampling and Quality Assurance Plan.

Phase 2

The purpose of Phase 2 is to design and implement a systematic program of sample

collection and analysis to fully characterize levels of health risk from long-term inhalation exposure to asbestos in air, and to identify any actual or potential sources and release mechanisms of asbestos. Specific tasks needed to implement Phase 2 will be selected after completion of Phase 1.

A6 QUALITY OBJECTIVES and CRITERIA for MEASUREMENT DATA

Two types of objectives are identified in this quality assurance project plan (QAPP): general objectives and data quality objectives (DQOs). General objectives are statements of practical goals that, if realized, will substantially contribute to achieving the purpose of the study. Development of DQOs is a process that is intended to ensure that task objectives are clearly defined and that data collected are appropriate and of sufficient quality to satisfy the objectives.

Phase 1 General Objective 1

Determine whether current airborne levels of asbestos in Libby are high enough to warrant a time-critical intervention.

Phase 1 General Objective 2

Obtain preliminary data on asbestos concentrations in potential source materials for air (e.g., dust, soil, mine waste), and determine the optimum conditions for sampling and quantifying asbestos levels in source materials.

Phase 2 General Objective

The general objectives for Phase 2 is to collect reliable and systematic data on asbestos levels in air and other media in Libby to allow a reliable evaluation of current human exposure and health risk from asbestos as well as an identification of sources of unacceptable levels of asbestos in air.

Data Quality Objective Process

The DQO process can be an iterative process which is designed to focus on the decisions that must be made and to help ensure that the site activities that acquire data are logical, scientifically defensible, and cost effective. The DQO process is intended to:

- Ensure that task objectives are clearly defined
- Determine anticipated uses of the data
- Determine what environmental data are necessary to meet these objectives
- Ensure that the data collected are of adequate quantity and quality for the intended use

The three stages of the DQO process are identified below and a discussion of how they have been applied in the characterization study described herein. The three stages are undertaken in an interactive and iterative manner, whereby all the DQO elements are continually reviewed and re-evaluated until there is reasonable assurance that suitable data for decision making will be attained.

- Stage I - Identify Decision Types: Stage I defines the types of decisions that will be made by identifying data uses, evaluating available data, developing a conceptual model, and specifying objectives for the project. The conceptual model facilitates identification of decisions that may be made, the end use of the data collected, and the potential deficiencies in the existing information.

- Stage II - Identify Data Uses/Needs: Stage II stipulates criteria for determining data adequacy. This stage involves specifying the quantity and quality of data necessary to meet the Stage I objectives. EPA's Data Usability for Risk Assessment Guidance (DURA) outlines general and specific recommendations for data adequacy. This includes identification of data uses and data types, and identification of data quality and quantity needs.

- Stage III - Design Data Collection Program: Stage III specifies the methods by which data of acceptable quality and quantity will be obtained to make decisions. This information is provided in the SOP.

Through utilization of the DQO process, as defined in EPA guidance (EPA540-R-93-071 and -078, Sep 1993), this QAPP will use several terms that are specifically defined to avoid confusion that might result from any misunderstanding of their use. For each of the tasks identified within this QAPP, a "Task Objective" is specifically defined. The Task Objective is a concise statement of the problem to be addressed by activities under this task. For each Task Objective, a decision (or series of decisions) is identified which addresses the problem contained in the Task Objective.

For each decision, the data necessary to make the decision are identified and described. For all analytical data, quality assurance objectives are specified that describe the minimum quality of data necessary to support the specified decision or test the hypotheses. These quality assurance objectives are specified as objectives for precision, accuracy, representativeness, comparability, and completeness. In addition, data review and validation procedures are specified in the QAPP that evaluate how well the analytical data meet these quality assurance objectives and whether or not the data are of sufficient quality for the intended usage.

The following sections apply the DQO process to the Libby Project, Stage I and Stage II. Stage III is discussed later (see Section B), but sampling and analysis methods presented in this section are considered tentative and final decisions on optimum sampling and analytical methods will be delayed until the findings of Phase 1 are available.

DQO Stage I - Identifying Decision Types

Stage I of the DQO process identifies a primary question and secondary questions that need to be resolved at the completion of the sampling and analyses program.

- PRIMARY QUESTION (Phase 1): Are current airborne levels of asbestos sufficiently high to warrant a time-critical intervention?

- SECONDARY QUESTION (Phase 1): What are the most likely sources of asbestos in air, and what are the best methods for quantifying asbestos levels in potential source materials?

DQO Stage II - Identifying Data Uses/Needs

Stage II of the DQO process also determines what type and quality of data are needed to answer the questions developed in Stage I. EPA has developed a seven-step method for developing the DQOs. This seven-step method is applied below in order to define the data requirements needed to achieve the primary and secondary objectives of the Phase 1 evaluation (and summarized in Table 1).

Primary Objective: Evaluate The Need For Time-critical Action

1. State the Problem

The problem to be addressed by this study is that citizens of Libby appear to have an increased incidence of asbestos-related disease, but there are no data to determine if this disease is attributable solely to historic exposures, or whether current exposures are of continuing health concern.

2. Identify the Decision

The first decision to be made is whether or not time-critical intervention is needed to protect public health. If current exposures are not high enough to warrant time-critical intervention, the next decision is whether or not non-time-critical remedial action is needed.

3. Identify Inputs to the Decision

Decisions on the need for time-critical intervention or non-time-critical remediation will be based on estimated risk of lung disease in current residents and workers in Libby. Two types of lung disease are of concern: asbestosis (a non-cancer effect) and lung cancer and

mesothelioma (cancer effects). Limited data suggest that chronic exposures to chrysotile fiber levels of 5-20 f/mL can cause asbestotic changes (ATSDR 1999), but data are not sufficient to derive a reliable chronic MRL or RfC for asbestosis. However, methods have been established for estimating the excess risk of lung cancer and/or mesothelioma, and it is considered likely that exposure levels that protect against unacceptable risk of lung cancer/mesothelioma (in the range of 0.1 to 0.0001 f/mL; see below) will also protect against unacceptable risk of asbestosis.

The basic equation used to estimate cancer risk is:

Risk = Concentration (f/mL) * Unit Risk (risk per f/mL)

Thus, the data needs are an **estimate of airborne asbestos concentration** and an **estimate of cancer risk per unit concentration**.

Measurement of Asbestos Concentration in Air

There are a number of techniques for measuring asbestos fibers in air, all of which are based on visual identification of structures as asbestos fibers. Most historical human health data and many regulatory limits for asbestos exposure in air are based upon asbestos fiber concentrations measured using phase contrast microscopy (PCM) (see Table 2). In this method, **fiber material** is defined as having a length >5 microns and an aspect ratio (length to diameter ratio) of three or more. Results are generally reported as fibers per milliliter of air (f/mL).

More recently, a number of other methods have been developed for quantitative or qualitative measurement of asbestos fibers in air, including transmission electron microscopy (TEM), and x-ray diffraction (XRD). These methods are generally more sensitive than PCM, and also allow visualization and quantification of asbestos fibers that are thinner than those visible under PCM. This is important because it is likely that the toxicity of long thin fibers is greater than that of shorter thicker fibers (Berman et al., 1995). Based on this, **asbestos fibers in air will be quantified by TEM.** Detailed rules for identifying asbestos fibers of biological concern by TEM are provided in ISO method 10312. This method is an international standard procedure that is recommended for quantifying asbestos fibers that are believed to be the chief source of human health concern (Berman and Crump 1999).

Unit Risk for Asbestos in Air

It is mandatory that the unit risk value used to calculate cancer risk be based on the same type of asbestos measurement technique as used to quantify asbestos concentration in air. That is, it is not correct to estimate risk by multiplying a concentration based on TEM fibers per mL by a unit risk based on PCM fibers per mL. Thus, risk-based values shown in Table 2 cannot be used

to interpret measurements based on TEM. EPA has developed a model for predicting risk from mesothelioma and lung cancer from TEM-based measurements of asbestos in air (USEPA 1986), and this method has been revised and improved by Berman and Crump (1999) to incorporate the influence of fiber length. The risk factors for the modified mesothelioma and lung cancer model are summarized in Table 3. Note that the risk factor depends not only on the number of TEM fibers greater than 5 um in length, but also on the fraction of all fibers that are longer than 10 um.

The toxicity factors shown in Table 3 are based on the best data currently available, but it is important to recognize that these toxicity factors are uncertain. This is because the values are derived from studies in which important details of exposure (level, duration, fiber size distribution, etc.) are not always known. In particular, the importance of fiber size (length, thickness) and fiber type (tremolite, chrysotile, etc.) on toxicity is difficult to quantify and remains a source of discussion.

4. Define the Study Boundaries

Spatial Bounds

The spatial bounds to be investigated in this project include the community of Libby, and areas associated with former mining activities near the town. Appropriate background areas may be selected for comparative evaluation.

Temporal Bounds

Asbestos fibers enter air mainly as a result of resuspension due to mechanical disturbance or wind erosion. Because mechanical and wind forces may vary substantially over time, asbestos levels in air are also expected to vary substantially over time. Thus, estimates of long term average concentrations are inherently preferable to measurements based on grab samples. Therefore, multiple samples of air will be collected over time at locations of interest. It is likely the highest levels will tend to occur in summer, when source areas tend to be dry and wind and mechanical forces result in significant dust resuspension.

5. Develop a Decision Rule

EPA must identify an actual or potential threat to human health or the environment in order to initiate a time-critical intervention at a site. Based on current EPA guidelines, a lifetime excess cancer risk of 1E-04 is considered to be at the upper end of the acceptable risk range for chronic (lifetime) exposure. Based on this, this Phase 1 study will use an excess cancer risk of about 1E-03 as the appropriate boundary for decision-making. That is, if asbestos levels in air correspond to an estimated cancer risk of about 1E-03 or higher, time critical actions to identify sources and find appropriate and effective interventions will be considered. If estimated cancer risks from asbestos in Phase 1 air samples do not exceed a level of about 1E-03, then further studies may be pursued to determine if risk levels might exceed 1E-03 at other times or in other places, or if risks might exceed an acceptable chronic risk level (e.g., 1E-04).

6. Specify Limits on Decision Errors

The null hypothesis that will be tested in Phase 1 is that indoor air levels in Libby are sufficiently high to warrant time-critical intervention. Two types of decision error are possible when making this decision:

Type I Error: Rejecting the null hypothesis when it really is true. That is, the site is declared to be below a risk level of 1E-03 when it is really above this level.

Type II Error: Accepting the null hypothesis when it actually is false. That is, the site is declared to be of time-critical concern when it actually is not.

The limits on these two types of errors are risk management judgements. In order to minimize the chances of a Type 1 error (a “false negative”), the decision will be based on the highest concentration of asbestos fibers detected in any currently-occupied residential or occupational building evaluated in the Phase 1 investigation. If one or more samples exceeds the 1E-03 risk level, time critical action may be needed. However, additional samples may be collected to confirm the original measurement and to refine the risk estimate. Because of the time variability in asbestos levels in air, final decisions may be delayed until additional data have been collected, including data in the summer when airborne resuspension and transport of asbestos fibers in outdoor air is considered to be more likely than in winter.

7. Optimize the Design for Obtaining Results

Additional indoor and/or outdoor air samples may be collected and incorporated into either Phase 1 and/or Phase 2 as data become available on actual airborne exposure and risk levels.

Secondary Objective: Preliminary Investigation of Source Materials

Table 4 provides a summary of the seven-step DQO process for achieving the secondary objective. The following text describes each of the DQO steps in detail.

1. State the Problem

The problem to be addressed by this portion of the study is that most methods currently available for measuring asbestos in solid materials (e.g., soil, dust, bulk insulation, mine waste, etc.) are relatively insensitive, and it is not known whether impacts of historic or ongoing asbestos releases on these media can be detected by these techniques.

2. Identify the Decision

The decision to be made is whether analysis of potential source materials and/or transport media in and about the mine (e.g., mine waste, surface water) and in and about the community of Libby (e.g., yard soil, house dust, garden soil) can be reliably quantified using available techniques. If so, then source areas judged to be of potential concern may be removed at the discretion of the OSC. Alternatively, additional sampling and analysis of potential source material may be pursed as needed to identify impacted areas and to focus on sources of unacceptable asbestos levels in air.

3. Identify Inputs to the Decision

Asbestos Measurements in Environmental Media

Inputs to the decision will be the results of asbestos analyses of each medium using the best available technique(s), as follows:

Medium	**Proposed Method**	
	Sample Preparation	**Sample Analysis**
Yard soil Garden soil Road soil Mine waste Bulk insulation	Collect bulk sample, place on slide	PLM of bulk material
	Collect bulk sample, dry	Visible reflective infrared spectroscopy
	Separate respirable dust fraction using Superfund method, collect dust on filter, collapse filter, prepare TEM grids	TEM of respirable dust
Indoor Dust	Microvacuum into cassette, suspend dust in water/alcohol, collect on filter, dry ash, prepare TEM grids	TEM
Surface Water	Collect bulk sample, filter, collapse filter, prepare TEM grids	TEM

These methods have been selected because they are judged to be the most likely to yield results that will allow qualitative or quantitative evaluation of asbestos levels in environmental media. Note that several alternative methods are identified for soil and related bulk materials. At present, it is not known which of these will be the most appropriate. It is envisioned that all samples will be screened using visible infrared spectroscopy, since this method is very fast and inexpensive. If successful, the results of this method can be used to rank-order samples into “high”, “medium” and “low” concentration ranges. For quantitative assessment, it is envisioned that all samples will be analyzed by PLM, since this method is fast and relatively less expensive than the Superfund TEM method. This evaluation will begin with samples that are known or suspected to

be high in asbestos concentration, based either on the infrared results and/or field observations such as the presence of visible levels of vermiculite, proximity to known sources or waste materials, etc. The analyses will continue through the samples to those that are known or suspected to contain "low" levels. When asbestos fiber concentrations are consistently below the detection limit, further analyses by PLM may be discontinued. After the results of the infrared and the PLM analyses are available, a set of samples will be selected for analysis by the Superfund method. This method is expected to be the most sensitive, because it includes a preliminary separation of respirable asbestos fibers from the bulk material, and because quantification is by TEM rather than PLM. However, the method is not yet in wide use, and is associated with a relatively high cost and slow turnaround time. It is for this reason that only about 15-21 samples will be evaluated by this approach. This set will be composed of approximately 5-7 in each of three categories: "high", "medium", and "low". Comparison of results across these three methods will allow an evaluation of which method(s) is (are) most appropriate for on-going evaluation of soils and related materials at the site.

For the other media (dust, surface water), all samples collected will be analyzed by the analytical methods indicated above. A comparison of results across samples will be used to determine whether the method is likely to be reliable and useful for further evaluation of site samples.

Community Interview

EPA will administer a community interview to numerous Libby residents including residents of each household sampled. These interviews will help gauge community members' level awareness about asbestos, their health concerns about asbestos, their knowledge about activities that may results in asbestos exposure, as well as possible sources of asbestos-bearing material. This information may help explain observed asbestos levels in samples from the home. A copy of the interview questionnaire is provided in Section E (Appendices).

4. Define the Study Boundaries

Spatial Bounds

The spatial bounds to be investigated in this project include the community of Libby, and areas associated with former mining activities near the town.

Temporal Bounds

Asbestos levels in source or transport material are expected to be relatively stable. Thus, the time when source area samples are collected is not judged to be critical.

5. Develop a Decision Rule

If no observable difference in asbestos concentration can be detected between the two classes of samples ("high" vs "low"), it will be concluded that a) either the medium is not impacted, or b) the measurement technique is not sufficiently sensitive. If a difference can be detected, it will be concluded that there is an impact to that medium, along with an actual or potential release to the environment, and that the current method can be used to further investigate and quantify that release.

6. Specify Limits on Decision Errors

Because the decision to be made is mainly with regard to method adequacy, no quantitative rules are needed to define decision errors.

7. Optimize the Design for Obtaining Results

Additional source area samples may be collected and incorporated into either Phase 1 and/or Phase 2 as data become available on the ability of current methods to detect and quantify asbestos fibers in each medium.

PARCC Requirements

Within this QAPP, quantitative and qualitative limits are defined for precision, accuracy, representativeness, comparability and analytical completeness. Reporting limits for asbestos fibers are set by the analytical laboratory based on environmental matrix, historical data, and comparison to EPA limits for CLP and other methods. Quantitative limits are also defined by microscopy (light microscopy or TEM) for method detection limits, and for method reporting limits or method quantitation limits. The QA procedures outlined in this section are intended to ensure data quality and to administer corrective actions with the goal of producing data that satisfy the following requirements. General guidelines, policies, and procedures to achieve these objectives are presented below. Where additional, detailed, procedures are required to attain QA objectives and to describe specific methods, these are provided in the SOPs (see attached). The following PARCC requirements apply to more standard chemical analytical analyses, and partially to asbestos analyses (e.g., identifying physico-chemical make-up of specific fibers)

Precision: Precision is defined as the agreement between a set of replicate measurements without assumption or knowledge of the true value. It is a measure of agreement among individual measurements of the same property under prescribed similar conditions. Agreement is expressed as either the relative percent difference (RPD) for duplicate measurements or the range and standard deviation for larger numbers of replicates. The RPD will be reported on required 5% laboratory duplicates.

Accuracy: Accuracy is a measure of the closeness of individual measurements to the "true" value. Accuracy usually is expressed as a percentage of that value. For a variety of analytical procedures, standard reference materials traceable to or available from National Institute of Standards and Technology (NIST, formerly National Bureau of Standards) or other sources can be used to determine accuracy of measurements. Accuracy will be measured as the percent recovery (%R) of an analyte in a reference standard or spiked samples (>3 at each selected concentration range) that span the limit of linearity for the method.

Ideally, precision and accuracy estimates should represent the entire measurement process, including sampling, analysis, calibration, and other components. From a practical perspective, these estimates usually represent only a portion of the measurement process that occurs in the analytical lab.

Representativeness: Representativeness is the degree to which data accurately and precisely represent characteristics of a population, parameter variations at a sampling point, or an environmental condition. For this QAPP, data and samples representative of chemical and biological exposures in the study and reference areas are to be collected from randomly chosen residences.

Comparability: Data are comparable if site considerations, collection techniques, and measurement procedures, methods, and reporting are equivalent for the samples within a sample set. A qualitative assessment of data comparability will be made of applicable data sets. These criteria allow comparison of data from different sources. Comparable data will be obtained by specifying standard units for physical measurements and standard procedures for sample collection, processing, and analysis. Please see the attached SOPs for sampling and analysis procedures.

Completeness: Data are considered complete when a prescribed percentage of the total intended measurements and samples are obtained. Analytical completeness is defined as the percentage of valid analytical results requested, and >90% of analyzed samples should have results reported. For this sampling program, a minimum of 80 percent of the planned collection of individual samples for quantification and a minimum of 30 percent of related parameters (e.g., physical measurements, fiber type, etc.) must be obtained to achieve a satisfactory level of data completeness.

Method Detection Limits (applicable to chemical analyses only): Method detection limits (MDLs) are minimum values that can be reliably measured to identify the analyte as being present in the matrix, versus method quantitation limits are the minimum values that can be quantitated with reasonable scientific confidence. The method will also have a maximum linear value in most situations, and analyses should occur within this limit of linearity range. See applicable operating procedures for details.

Table 1. DQOs for Primary Objective: Evaluate the Need for Time-Critical Action

DQO Step	Description
1. Define the problem	The citizens of Libby appear to have an increased incidence of asbestos-related disease, but there are no data to determine if this disease is attributable solely to historic exposures, or whether current exposures are of continuing health concern.
2. Identify the decision	Is time-critical action needed to protect public health? If yes, identify appropriate action and intervene as necessary If no, determine whether or not non-time-critical remediation is necessary
3. Identify inputs to decision	Level of concern for human health (lifetime excess cancer risk of 1E-03) Estimate of airborne asbestos concentration, and cancer risk per unit concentration.
4. Define study boundaries	*Spatial bounds*: Community of Libby, including former mining, milling and processing areas and areas potentially impacted as defined by meteorological conditions. If necessary, appropriate background areas are also included (precise locations to be defined). *Temporal bounds*: multiple air samples will be collected in areas associated with former mining activities near the town seasonally throughout the year
5. Define decision rule	If asbestos levels in indoor air $\geq$ 1E-03 risk level, consider the need for time-critical intervention. If asbestos levels in indoor air < 1E-03 risk level, time-critical intervention may not be necessary. However, additional studies may be needed to determine if non-time-critical remediation is necessary, or if levels might exceed 1E-03 risk levels under different conditions (e.g., seasonal variation)
6. Specify limits on decision errors	Risk management decisions will be based on the highest airborne asbestos concentration found in any residential or occupational building.
7. Optimize the design	Incorporate new information as data become available on actual airborne exposure and risk levels.

Table 2: Summary of Available PCM-Based Exposure Levels for Asbestos

Agency	Description	Nominal Value	Reference
ACGIH	TLV-TWA	0.1 f/cc	ACGIH, 1998
NIOSH	REL 100 minute TWA in a 400L sample (all forms)	0.1 f/cc	NIOSH 1999
OSHA	PEL (TWA) all forms	0.1 f/cc	OSHA 1998 29 CFR 1919.1001
OSHA	PEL (ceiling) 30 minute average - all forms	1.0 f/cc	OSHA 1998 29 CFR 1926.1101
EPA (IRIS)	Inhalation unit risk - all forms	0.23 per (f/mL)	IRIS 1999
EPA (OW)	MCL (f>10 um in length) all forms	7 MFL[a]	EPA 1998

[a] MFL = million fibers per liter

TABLE 3. Unit Risk for Inhalation of Asbestos

Population	Percentage of Fibers Greater than 10 um in Length										
	0.50%	1%	2%	4%	6%	10%	15%	20%	30%	40%	50%
Male Nonsmoker											
Lung Cancer	1.0E-02	1.6E-02	3.0E-02	5.4E-02	8.0E-02	1.3E-01	1.9E-01	2.6E-01	3.8E-01	5.0E-01	6.4E-01
Mesotheliomas	1.1E-01	1.9E-01	3.2E-01	6.2E-01	9.0E-01	1.5E+00	2.2E+00	2.9E+00	4.3E+00	5.8E+00	7.2E+00
Total	1.2E-01	2.0E-01	3.5E-01	6.7E-01	9.8E-01	1.6E+00	2.4E+00	3.2E+00	4.7E+00	6.3E+00	7.8E+00
Female Nonsmoker											
Lung Cancer	7.6E-03	1.2E-02	2.2E-02	4.0E-02	6.0E-02	9.6E-02	1.4E-01	1.9E-01	2.8E-01	3.8E-01	4.8E-01
Mesotheliomas	1.3E-01	2.0E-01	3.6E-01	6.8E-01	1.0E+00	1.7E+00	2.5E+00	3.3E+00	4.9E+00	6.5E+00	8.1E+00
Total	1.4E-01	2.1E-01	3.8E-01	7.2E-01	1.1E+00	1.8E+00	2.6E+00	3.5E+00	5.1E+00	6.8E+00	8.5E+00
Mean Total for Nonsmokers	2.6E-01	4.1E-01	7.3E-01	1.4E+00	2.0E+00	3.4E+00	5.0E+00	6.6E+00	9.8E+00	1.3E+01	1.6E+01
Male Smoker											
Lung Cancer	9.4E-02	1.5E-01	2.6E-01	5.0E-01	7.4E-01	1.2E+00	1.8E+00	2.4E+00	3.5E+00	4.7E+00	5.9E+00
Mesotheliomas	7.6E-02	1.2E-01	2.2E-01	4.2E-01	6.0E-01	9.8E-01	1.5E+00	1.9E+00	2.9E+00	3.8E+00	4.8E+00
Total	1.7E-01	2.8E-01	4.8E-01	9.2E-01	1.3E+00	2.2E+00	3.2E+00	4.3E+00	6.4E+00	8.5E+00	1.1E+01
Female Smoker											
Lung Cancer	6.4E-02	1.0E-01	1.8E-01	3.4E-01	5.0E-01	8.2E-01	1.2E+00	1.6E+00	2.4E+00	3.2E+00	4.0E+00
Mesotheliomas	1.1E-01	1.9E-01	3.2E-01	6.2E-01	9.0E-01	1.5E+00	2.2E+00	2.9E+00	4.3E+00	5.8E+00	7.2E+00
Total	1.8E-01	2.9E-01	5.0E-01	9.6E-01	1.4E+00	2.3E+00	3.4E+00	4.5E+00	6.7E+00	9.0E+00	1.1E+01
Mean Total for Smokers	1.7E-01	2.8E-01	4.9E-01	9.4E-01	1.4E+00	2.2E+00	3.3E+00	4.4E+00	6.6E+00	8.8E+00	1.1E+01

Source: Berman and Crump (1999)

Table 4. DQOs for Secondary Objective: Preliminary Investigation of Source Materials

DQO Step	Description
1. Define the problem	Optimum sampling and analysis techniques for potential source media (soil, dust, mine waste, etc) are not known and available techniques may or may not be able to detect and quantify impacts of asbestos releases
2. Identify the decision	Can asbestos concentrations be reliably quantified using available methods? If yes, source areas may be characterized and removed at the discretion of the OSC If no, additional methods development may be required
3. Identify inputs to decision	Asbestos measurements from selected samples that are expected to have “high” and “low” asbestos levels. Compare results to determine if available methods are sufficiently sensitive to detect and measure differences in potential source materials and/or transport media. Survey information on historic and current factors that may help explain current patterns of asbestos contamination
4. Define study boundaries	*Spatial bounds*: Community of Libby and areas associated with former mining activities near the town *Temporal bounds*: because asbestos levels in source or transport material are relatively stable, the time when these samples are collected is not critical
5. Develop decision rule	If no difference is observed between the two classes of samples, the following conclusions will be drawn: a) the medium is not impacted, or b) the measurement technique is not sufficiently sensitive If a difference between the two classes of samples **can** be detected, the following conclusions will be drawn: a) the medium is impacted b) the method can be used to further investigate and quantify that impact
6. Specify limits on decision errors	NA
7. Optimize the design	Additional source area samples may be collected and incorporated as data becomes available on the ability of current methods to detect and quantify asbestos fibers in each medium

B. MEASUREMENT AND DATA ACQUISITION

B1 SAMPLING PROCESS DESIGN

Study Area: For this investigation, the study area is Libby, MT. Initial sampling will be based upon identification of community volunteers. Initial sampling will consist of two basic parts : 1) sampling in residential areas, including the collection of samples at approximately 30 volunteer residences in Libby, along with samples from appropriate background residential areas not influenced by vermiculite mining, and 2) sampling at suspected asbestos source areas and/or transport pathways. All field samples will be accompanied by appropriate QA/QC (5-20%) samples. If possible, future sampling will be based upon stratified random sampling design to select homes in Libby and appropriate reference areas. Additional samples will be targeted at reference areas. Within each area, homes will be selected semi-randomly and on a volunteer basis and access requested from owners. Sampling will be conducted to improve an understanding of actual or potential exposure pathways as indicated in the Conceptual Site Model (Figure 1).

Sample size and characteristics: For this study, approximately 30 residences will be targeted for sampling. In addition to sampling in these residences, samples may be collected as requested by City or State Officials in public buildings, schools, and/or hospitals. Samples collected at residential locations will usually include indoor air, indoor dust and outdoor soil. Samples collected at suspected source and/or transport media may include mine waste, outdoor soil, surface water, sediment and outdoor air, as judged appropriate by the OSC.

B2 SAMPLING METHODS REQUIREMENTS

Air

Air samples will be collected by drawing air through a cellulose acetate filter (0.45 um pore size) at a specified flow rate for a specified period of time. The details of the method are provided in SOP 2015. The optimal conditions for sample collection depend on the level of health risk that is of concern, the level of asbestos in the air, and the level of interfering particles in air besides asbestos. Presented below is a set of alternative flow conditions that illustrate the range of sampling and analysis conditions that may be needed to achieve differing levels of sensitivity.

Alternative Air Sampling and Analysis Methods

Target Risk	Assumed Percent Fibers > 10 um in Length	Concentration of Concern (f/mL) (a)	Suggested Sampling and Analysis Parameters (b)			
			Grid Openings	V (L)	Flow (L/min)	Time (hrs)
1.0E-02	1%	3.5E-02	4	900	1	15
	10%	4.5E-03	8	3800	3	21
1.0E-03	1%	3.5E-03	10	4000	10	7
	10%	4.5E-04	40	8000	10	13
1.0E-04	1%	3.5E-04	40	8500	10	14
	10%	4.5E-05	60	50000	16	52

(a) Based on average unit risk to smokers (see Table 3). As noted in the text, quantitative toxicity values for asbestos-induced cancer are uncertain, and so the concentration values listed should not be viewed as discrete boundaries between “acceptable” and “unacceptable”.

(b) Grid openings and air volume required to quantify asbestos at approximately 1/3 the target risk level.

The collection conditions in the shaded row correspond to the conditions that were selected for initial samples collected in Phase 1. Depending on the ratio of long fibers to total fibers, and on the level of interfering non-asbestos dust, these samples may have a risk detection limit of about 3E-04, sufficiently low to assess the potential need for time critical action.

Soil

Bulk samples (mine waste, yard soil, garden soil, road material, insulation, etc.) will be collected, stored under chain-of-custody, and shipped according to methods outlined in Standard Operating Procedures supplied by CDM, Inc., including SOP 4-1 (Field Logbook Content and Contro), SOP 1-3 (Surface Soil Sampling), SOP 1-2 (Sample Custody), SOP 2-5 (Packaging and Shipping of Environmental Samples), SOP 4-2 (Photographic Documentation of Field Activities), and the Surface/Subsurface Soil Sampling Log (Attached).

Dust

Dust sampling will be conducted using method D 5755 - 95 (structure, number count) provided by the American Society for Testing and Materials (ASTM) (Attached).

Surface Water

Surface water is unlikely to be a source of airborne asbestos fibers, but can serve as a transport pathway. Samples of surface water will be collected according to SOP 2013.

Field QA/QC Samples

The QA/QC samples will consist of field blanks (air and dust only), duplicate samples, background samples collected in areas expected to be unaffected by vermiculite mining. Every reasonable effort will be made to adhere strictly to specified SOPs. Where deviation from SOPs is unavoidable, documentation of the deviation and its potential impact on the outcome of the data collection effort will be clearly indicated in field notes and subsequent reports. Detailed field notes will record information pertinent to each sample collection. These field notes will be indexed and made available for review following sample collection.

B3 SAMPLING, HANDLING AND CUSTODY REQUIREMENT

Documentation of sample collection, handling, and shipment will include completion of chain-of-custody forms in the field, use of field maps and field forms, and entry of data into a field logbook. Each sample will be properly labeled with the a unique sample identifier. A chain-of-custody form shall accompany every shipment of samples to the analytical laboratory. The purpose of the chain-of-custody form is to establish the documentation necessary to trace possession from the time of collection to final disposal. Figures 2 to 5 summarize the sampling, handling, and analyzes for each media type.

The chain-of-custody will be designated by CDM SOP 1-2. Minimally the field form will have the following information:

- Project number
- Sampler's signature
- Date and time of sample collection
- Sample identification number
- Analytical parameters

The shipping forms or transmittal memo from EPA will describe:

- Number of containers
- Sample preservative (N/A)
- Date and time of sample shipments

The labs will enter the following information upon receipt:

- Name of person receiving the sample
- Date of sample receipt
- Sample condition

All corrections to the chain-of-custody record will be initialed and dated by the person making the corrections. Each chain-of-custody form will include signatures of the appropriate

individuals indicated on the form. The originals will accompany the samples to the laboratory, and copies documenting each custody change will be recorded and kept on file.

Chain-of-custody will be maintained until final disposition of the samples by the laboratory and acceptance of analytical results by EPA. One copy of the chain-of-custody will be kept by field personnel.

The microscopist will include the following information on the Field Form:

- Date
- Microscopist's name
- Sample identification
- Mineral Type
- Structure Counts

All required paper work, including sample container labels, chain-of-custody forms, custody seals and shipping forms will be fully completed in ink (or printed from a computer) prior to shipping of the samples to the laboratory. Shipping from sample storage to laboratory will be by overnight delivery.

Upon receipt, the samples will be given to the laboratory sample custodian. The coolers will be opened and the contents inspected. Chain-of custody forms will be reviewed for completeness, and samples will be logged and assigned a unique laboratory sample number. Any discrepancies or abnormalities in samples will be noted. The EPA On Scene Coordinator will maintain original log books and receive all data packages and reports.

B4 ANALYTICAL METHODS REQUIREMENTS

The most appropriate analytical methods for each environmental medium may depend on the type and level of asbestos contamination and on the detection levels needed to assess hazard and/or nature and extent of contamination. For these reasons, the final choice of method for each medium cannot be specified at this time. A number of methods that are considered reliable and that may be utilized in this investigation are provided as SOPs in Section E (Appendices).

In most of these methods, two alternative approaches are available: "direct" and "indirect" analysis. In direct analysis, the sample is prepared with minimal handling, generally by collecting the sample on a filter or by placing the test material directly under the microscope for examination. However, this approach may sometimes be inadequate because a) the fibers are accompanied by an excessive level of non-asbestos material, or b) the concentration of asbestos fibers is either too low or too high for reliable quantification. In these cases, an indirect approach will be considered. In this approach, the sample is generally diluted, concentrated, and/or treated to remove interferences, such that the asbestos fibers can be more reliably quantified. However,

because indirect preparation steps may alter fiber morphology and/or may alter fiber recovery, indirect sampling will be avoided whenever possible.

B5 QUALITY CONTROL REQUIREMENT

The project team organization ensures attainment of QA objectives by:

- Assigning responsibility for performing work according to specifications
- Providing oversight of quality-related activities for verification of conformance with specifications
- Defining the relationships between management and personnel performing quality-related work Corrective Action

The Project Manager will prepare a summary of quality-related activities and problems. This summary will be forwarded to EPA for inclusion in the project file. If deficiencies in the program are identified, the Project Manager will identify recommendations for corrective action.

Communications. Lines of communication between project personnel and project management staff will be appropriate to enable timely response to events that have the potential to affect data quality. Project personnel will be provided with a project contact list that includes telephone numbers for both routine communications and emergency notifications.

Communications will also entail ensuring that information on sample collection, transportation, analysis, and storage; data acquisition, analysis, and reporting; personnel assignments and activities; and other information pertinent to the project are distributed to potentially affected personnel in a timely manner. Changes in procedures, equipment, personnel, or other program elements as a result of an accident or emergency that have the potential to affect data quality or achievement of overall program objectives will be communicated to the Project Manager in writing in a timely manner. Copies of all written communications and written summaries of all substantive telephone conversations will be placed in a permanent project file maintained by the EPA On Scene Coordinator.

Quality Control Methods. Quality control methods will include both a field and laboratory component. Field personnel will prepare two types of quality control samples: replicates and blanks.

Replicates - For air samples, replicates are defined as separate samples that are collected using separate air pumps and filters. These air samples are collected side-by-side at a location and are sampled for the same amount of time. Air pumps are set at the same air flow rates so that adequate and like air volumes are passed through each filter. Replicate samples will not be collected for any media other than air.

Blanks - Field personal will prepare blank samples for air and dust by labeling un-used filter cassettes and submitting them for analysis.

The laboratory and its staff will have the responsibility for processing all samples submitted according to the specific protocols for sample custody, analysis, reporting, and associated laboratory QA/QC. Laboratory personal will prepare blanks TEM grids from the same lot of filters used to prepare water and soil samples.

Quality assurance programs for analytical chemistry typically include blanks, blind standards, and spikes. Unfortunately, this type of performance evaluation program is not available for asbestos analysis. The laboratory quality assurance program will consist of blanks and replicate analysis. Blank samples will be used to control for possible contamination in the filter medium. A subset of TEM grids (10-20%) will be sent either back to the primary laboratory for re-analysis (blind) or to additional laboratories for replicate analysis. The TEM grids for replicate analysis will be shipped under chain of custody to appropriate laboratories for analysis.

B6 INSTRUMENT CALIBRATION and FREQUENCY

Pumps used for air sampling will be calibrated just prior to sampling and again at the termination of sampling to determine air flow rates across the sampling.

SOPs will identify requirements needed to be met by the laboratories to meet adequate instrument calibration frequency, and QA/QC for raw data and reports.

C. ASSESSMENT OVERSIGHT

C1 ASSESSMENTS and RESPONSE ACTIONS

The EPA On Scene Coordinator and/or Scientific Support Coordinator will be on-site to oversee and inspect sampling activities. Enough sample will be taken and archived to allow for problems (such as loss or spoilage) from transportation or analytical labs.

D. DATA VALIDATION and USABILITY

D1 DATA REVIEW, VALIDATION and VERIFICATION REQUIREMENTS

Data validation will consist of a) establishing an absolute range, acceptance limits (screening criteria), and appropriate statistics for each data parameter, b) describing methods for determining the disposition of suspect data, and c) documenting final disposition of invalid or qualified data, including outliers.

Test Statistic: Quantitative professional judgement will be used to determine fiber counts in sampled media. Toxigenic hazard will be assessed based upon professional identification of asbestos fibers. Toxigenic potential of specific fibers will be determined by thorough review of the peer reviewed literature as well as be professional judgement of qualified toxicologists, physicians, and or industrial hygienists.

If feasible, based upon sampling success, a **one-tailed t-test** will be used to compare the two groups (test area and background or reference area) for appropriate classes of asbestos fibers and/or fiber sizes identified (a two-tailed t-test is not used since any change in fiber concentrations is expected to be one direction above background levels as per EPA Risk Assessment Guidance). If there is statistical probability of (e.g. a # 0.05) for Libby residences being higher than reference areas, then reject the null hypothesis and conclude that significant difference exists between the two groups for a particular fiber type. Therefore, potential exposure of humans to this species would not be able to be screened out. Conversely, if (e.g.) a $ 0.05 for all appropriate fiber sizes and fiber types in a specific media that is reasonably well defined and comparable with similar media in the test area (i.e., no “hot-spots”), then the null hypothesis is accepted and exposure via this route is able to be screened out with no further evaluation being justifiable.

Out-of-range data (fibers outside of the size range normally considered to be toxigenic) will be excluded from the validated data set unless the appropriate data value and relevant toxicological significance can be positively established and documented. Other suspect data or samples will be examined in detail, including any irregularities in its collection and handling. In the absence of any clear indication that they are invalid (such as equipment failure or operator error), data outliers will remain in the validated data set but will be flagged as outliers per specified criteria (e.g., >3 x SD from the mean). Data points determined to be invalid will be permanently flagged in a clear and consistent manner in the original raw data set and removed from subsequent data summaries and files.

QA for data validation will ensure that the screening criteria are comprehensive, unambiguous, reasonable, and internally consistent; and that data validation activities are properly documented. Data discrepancy reports should be prepared describing any data problems observed and any data correction activities undertaken.

Data analysis will consist of analyzing valid data sets from residential results to provide information in formats appropriate to the objectives of the exposure screening study. All data records should be cataloged and stored in their original form. Calibration adjustments and adjustments to reduce data to standard conditions for comparability will be clearly documented, and raw data clearly distinguished from "corrected" data (i.e., data to which calibration and standardization adjustments have been applied).

Raw data and adjustments should be entered into a computer database and/or spreadsheet for correction, statistical analysis, manipulation, formatting, and summarizing to reduce the potential for human error. EPA requests that all data be placed into the designated data entry sheets.

D2 VALIDATION and VERIFICATION METHODS

Data reporting consists of communicating summarized data in a final form. Quality assurance for reporting consists of measures intended to avoid or detect human error and to correct identified errors. Such methods include specification of standard reporting formats and contents of measures to reduce data transcription errors. Data will undergo peer review by qualified reviewers capable of evaluating reasonableness of the data for the scientific design.

Reports: A report of all the summary study design characteristics, sample collections and analyses, data quality and results shall be presented by the analytical laboratories. Simple statistical tests of group treatment differences should be performed and presented as discussed above and will be conducted by EPA. All raw data and summary results of both data and summary statistics (means, standard deviations, ranges, etc.) should be tabulated by the laboratories. Results should be interpreted to quantitatively estimate the relative frequency of occurrence of specific asbestos fibers above reference levels. Study reports should be available within 60 days of receipt of acceptable laboratory results and reports.

Data will be reviewed by the On Scene Coordinator, EPA Science Support Coordinator and State officials, and by a peer review team to assess data quality in accordance with DURA (1992) for this CERCLA Emergency Response site.

Quality assurance records and project files will be maintained in accordance with standard project procedures. All QA records, logbooks, sample data forms, raw data summaries, and the like will be maintained until written directions for their disposal are provided.

D3 RECONCILIATION with DQOs

The project team will review any results which fall outside the DQOs and decide (per DURA 1992 and RAGS 1992) the extent of useability of results for risk assessment.

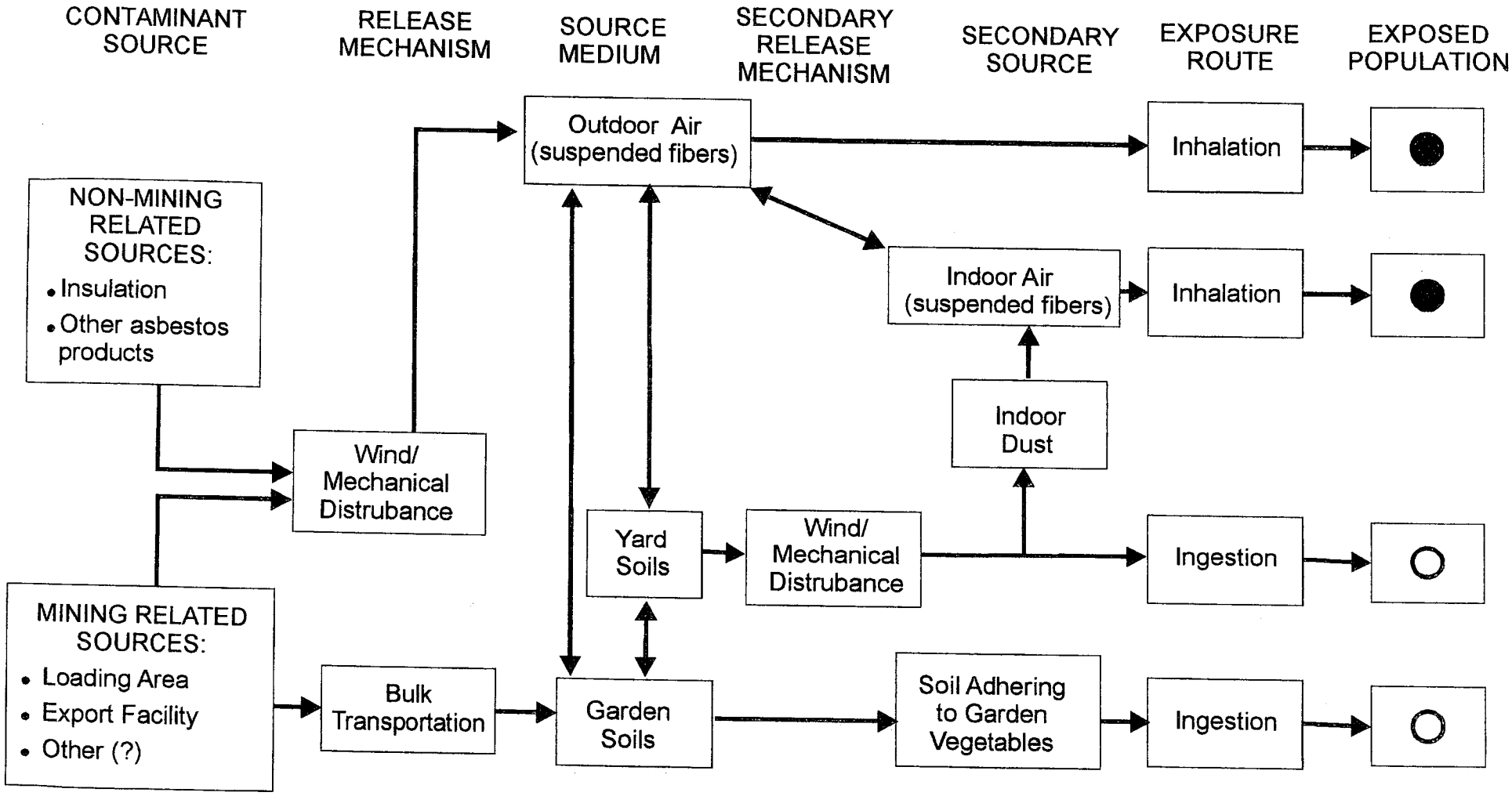

Figure 1. Draft Conceptual Site Model - Potential Human Exposure Pathways to Asbestos at the Libby, Montana Site

○ = Pathway is complete, but minor; qualitative evaluation

● = Pathway is complete and could be significant; quantitative evaluation

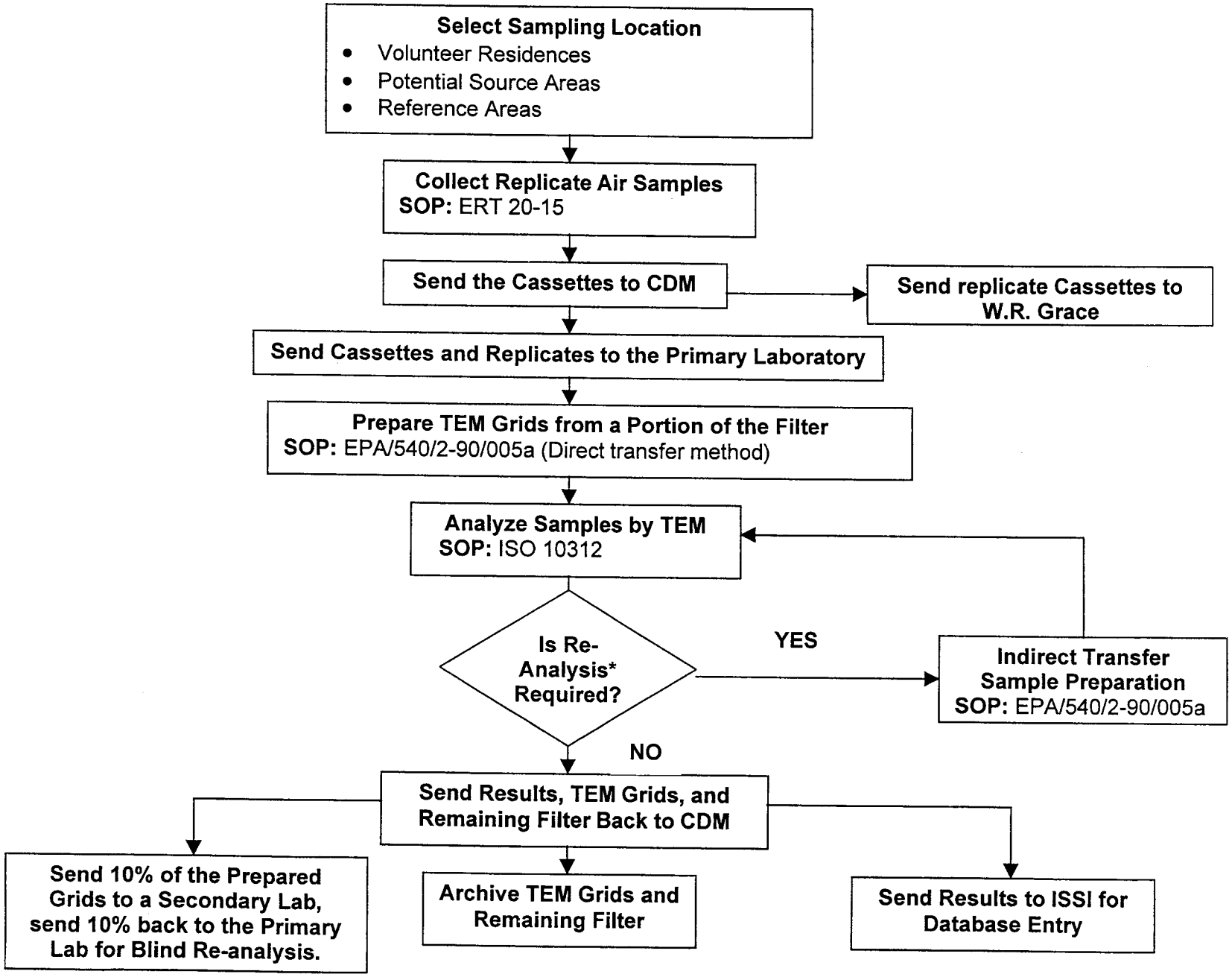

Figure 2. Air Sample Flow-Diagram

*For details on when re-analysis is required refer to the text.

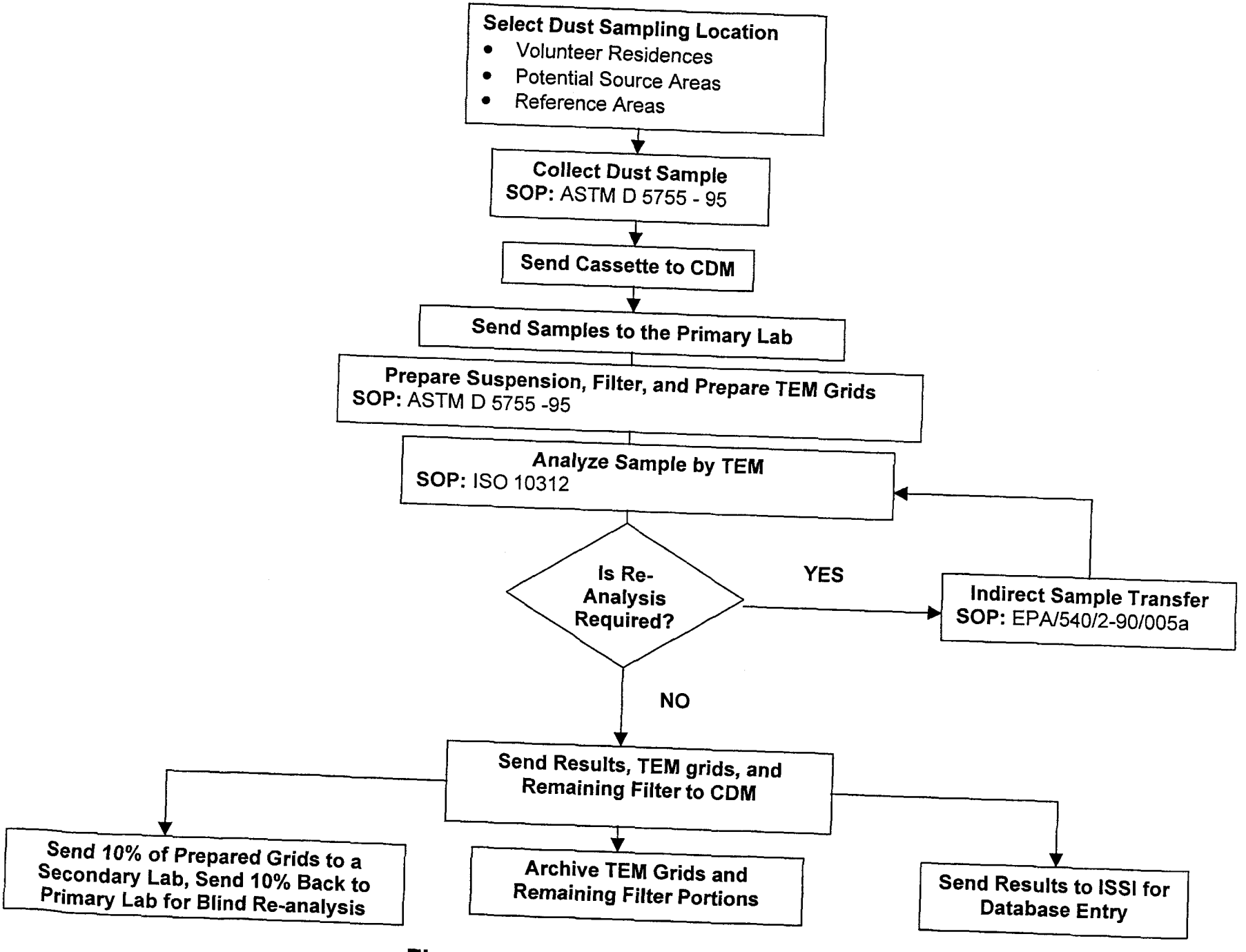

Figure 3. Dust Sample Flow Diagram

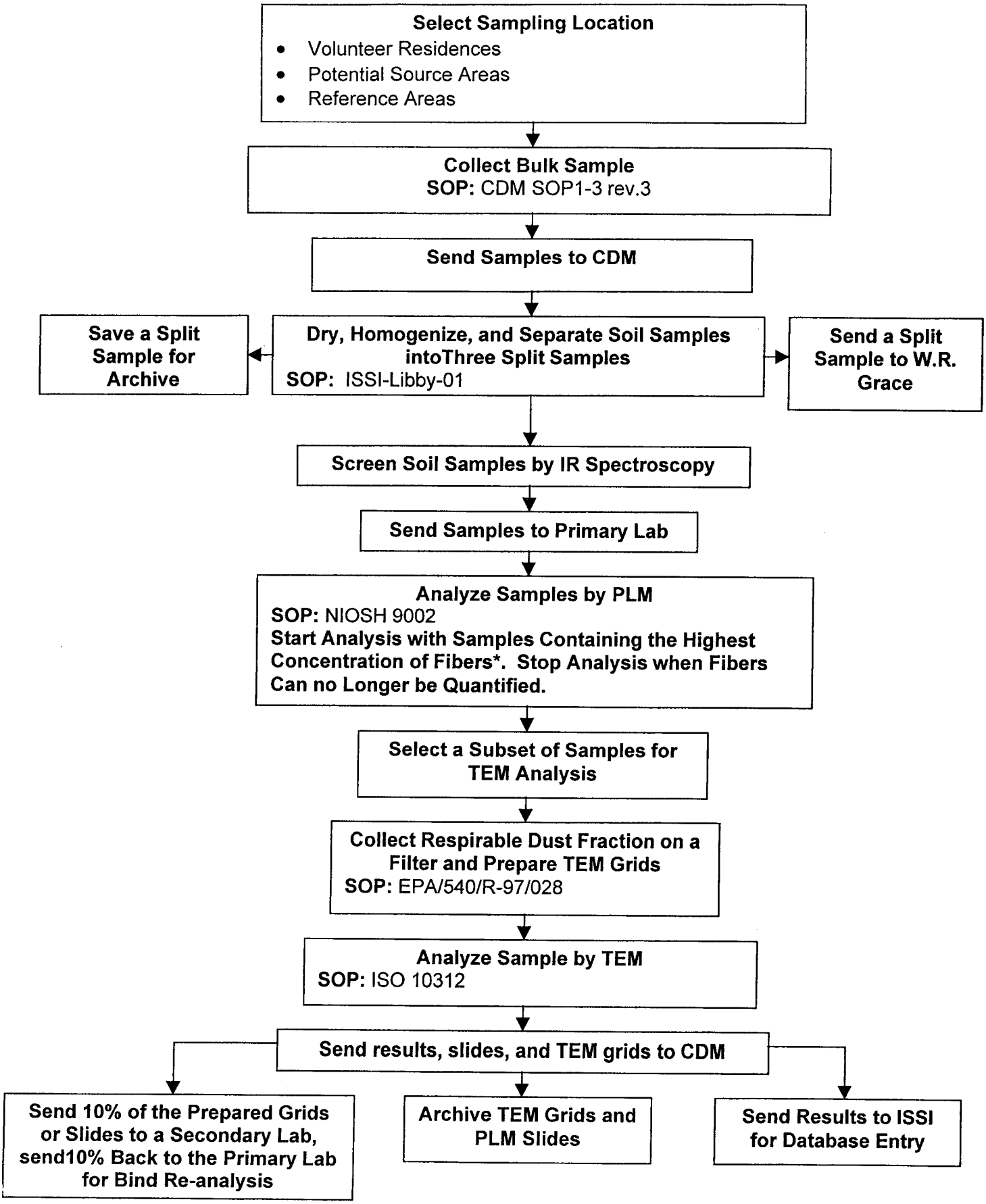

Figure 4. Sample Flow Diagram for Soil and Other Bulk Materials

*Refer to the text for a description of how the samples with the highest concentration of fibers will be selected.

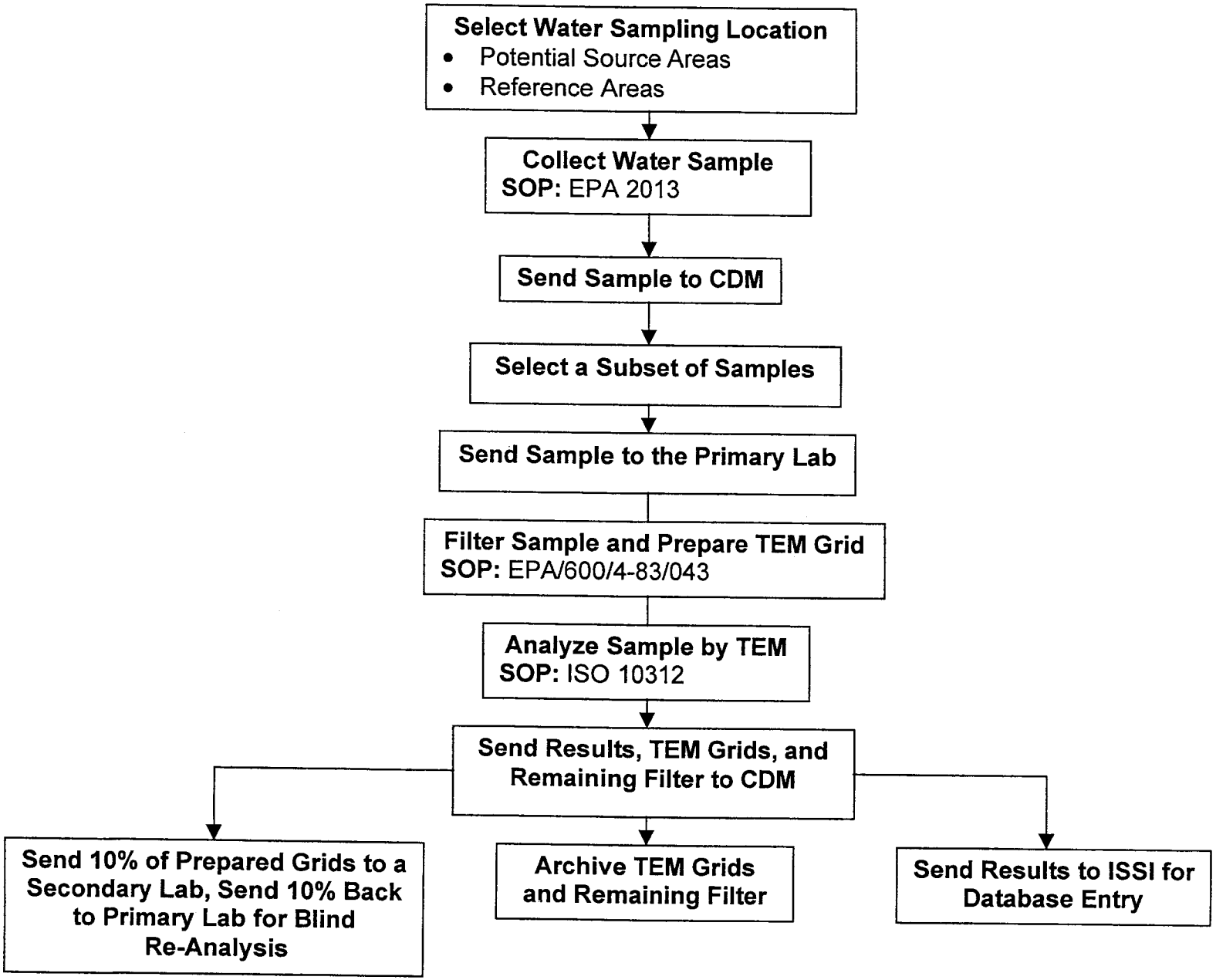

Figure 5. Water Sample Flow-Diagram

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E. APPENDICES

Appendix	Title	
1	Community Interview for Residents of Libby, Montana	
2	SOP 4-1	Field Logbook Content and Control
3	SOP 1-3	Surface Soil Sampling
4	SOP 1-2	Sample Custody
5	SOP 2-5	Packaging and Shipping of Environmental Samples
6	SOP 4-2	Photographic Documentation of Field Activities
7	SOP 4-5	Field Equipment Decontamination at Non-Radioactive Sites
8	Surface/Subsurface Soil Sampling Log	
9	ASTM D 5755-95	Microvacuum Sampling and Indirect Analysis of Dust by Transmission Electron Microscopy for Asbestos Structure Number Concentrations
10	NIOSH Method 9002	Asbestos (bulk) by PLM
11	ISO 10312	Ambient Air - Determination of Asbestos Fibers: Direct -Transfer Transmission Electron Microscopy Method
12	EPA SOP 2015	Asbestos Sampling
13	ISSI- Libby-01	Soil Sample Preparation
14	EPA 540/2-90/005a	Superfund Method for the Determination of Asbestos in Ambient Air
15	EPA 540-R-97-028	Superfund Method for the Determination of Releasable Asbestos in Soil and Bulk Materials
16	EPA SOP 2013	Surface Water Sampling
17	EPA 600/4-84-043	Analytical Method for Determination of Asbestos Fibers in Water
18	ASTM D 3195 -90	Standard Practice for Rotameter Calibration
19	ISSI-Libby-02	Reflectance Spectroscopy Screening for Asbestos in Soil